IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

LAUREN DICAIR, ADMINISTRATRIX OF THE ESTATE OF BRUCE G. DICAIR, Plaintiff,	:	**CIVIL ACTION**
v.	:	
GILEAD SCIENCES, INC. et al., Defendants.	:	**No. 21-5486**

MEMORANDUM

Schiller, J. **July 12, 2022**

Before the Court is Defendants Gilead Sciences, Inc. and Asegua Therapeutics LLC's (together, "Gilead and Asegua") Motion to Dismiss Plaintiff Lauren DiCair's Complaint. Plaintiff, as administratrix of the estate of her late father Bruce DiCair ("Decedent"), alleges that Gilead and Asegua[1] are liable for the death of her father because their medication caused Decedent to develop liver cancer. Plaintiff asserts failure to warn, design defect, and manufacturing defect claims under theories of both negligence and strict liability. The Court finds that Plaintiff has plausibly stated a

[1] The Complaint names two other defendants: Gilead Science, Inc. and Gilead Pharmassett LLC. Gilead and Asegua assert that "Plaintiff erroneously named 'Gilead Science, Inc.' and 'Gilead Pharmassett LLC' as Defendants in the caption" for two reasons. (ECF No. 3 at 5.) First, Gilead and Asegua state that neither entity is known to them or affiliated with properly named defendant Gilead Sciences, Inc. Second, they maintain that although Gilead "Pharmasset" LLC—spelled with one "t"—is an indirect, wholly-owned subsidiary of Gilead Sciences, Inc., Plaintiff did not properly serve Gilead "Pharmassett" LLC with process in this action. (*Id.*) They point to the Certificate of Service to the Complaint, wherein Plaintiff states that she served Gilead "Pharmassett" LLC via first class mail. This does not comport with Pa. R. Civ. P. 403-04, which requires that a "copy of the process shall be mailed to the defendant by any form of mail requiring a receipt signed by the defendant or his authorized agent." Pa. R. Civ. P. 403; *see also Egli v. Strimel*, Civ. A. No. 14-6204, 2015 WL 5093048, at *1 n.1 (E.D. Pa. Aug. 28, 2015). Plaintiff has not responded to or addressed these allegations in her opposition or elsewhere. Accordingly, the Court dismisses Gilead Science, Inc. and Gilead Pharmassett LLC as parties to this action.

claim only for negligent manufacturing defect and design defect. For the reasons below, the Court will grant Defendants' motion in part and deny it in part.

I. BACKGROUND

Gilead and Asegua design, produce, manufacture, sell, and market a prescription medication known as ledipasvir-sofosbuvir, sold under the trade name Harvoni. (Compl. ¶ 13.) Harvoni is used to treat hepatitis C. (*Id.* ¶ 15.) On or after September 27, 2017, Decedent was prescribed Harvoni, which he took according to the dosage instructions. (*Id.* ¶ 17.) After he began taking Harvoni, Decedent developed Hepatocellular Carcinoma, a form of liver cancer. (*Id.* ¶ 18.) Decedent died on December 19, 2018. (*Id.*) Plaintiff, the daughter and administratrix of Decedent's estate, asserts that Decedent's Hepatocellular Carcinoma—and, consequently, his death—was caused by Harvoni.

The Complaint asserts four causes of action. Gilead and Asegua moved to dismiss the Complaint in its entirety on December 23, 2021. (ECF No. 3.) Plaintiff withdrew Counts Two and Three—claims for breach of express warranty and breach of implied warranty, respectively—on January 12, 2022. (ECF No. 7.) Counts One and Four, the remaining counts, assert claims of "Negligence" and "Products Liability," respectively. Count One asserts that Gilead and Asegua acted negligently "in the design, manufacture, production, licensing, distribution, marketing, testing, and sale of" Harvoni, in addition to "failing to warn of [Harvoni's] defects and dangerous and harmful capabilities." (Compl. ¶ 20.) Count Four asserts that Gilead and Asegua "sold [Harvoni] in a defective condition" and "failed to warn of the risk of the development of Hepatocellular Carcinoma as a result of taking [Harvoni]" and, accordingly, are "strictly liable to Plaintiff." (*Id.* ¶¶ 48-49, 51.)

The Court notes that, in pleading Counts One and Four, Plaintiff appears to have confused *claims* with *theories of liability*. "Products liability" is type of *claim* a plaintiff may assert when a product—including a drug—causes them damage. That claim can sound in different legal *theories of liability*, whether negligence or strict liability. *See* Joseph A. D'Angelo et al., *3A Summ. Pa. Jur. 2d Torts* § 41:119 (2d ed. 2022). Here, although Plaintiff pleads Count One as a claim for "Negligence" and Count Four as a claim for "Products Liability," the Court will treat both as claims for products liability, the former sounding in negligence and the latter sounding in strict liability. (*See* Compl. ¶¶ 22 (stating in Count One that "[t]he Decedent's development of Hepatocellular Carcinoma was caused solely by the negligence of Defendants"), 51 (stating in Count Four that "Defendants are strictly liable to Plaintiff").)

II. STANDARD OF REVIEW

In deciding a motion to dismiss for failure to state a claim pursuant to Fed. R. Civ. P. 12(b)(6), the Court must accept as true all well-pleaded factual allegations in the complaint and make all reasonable inferences in favor of the non-moving party. *Bd. of Trustees of Bricklayers & Allied Craftsmen Loc. 6 of N.J. Welfare Fund v. Wettlin Assocs., Inc.*, 237 F.3d 270, 272 (3d Cir. 2001). A well-pleaded complaint "require[s] only a short and plain statement of the claim showing that the pleader is entitled to relief" and need not contain "detailed factual allegations." *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 232-34 (3d Cir. 2008) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007)). To survive a motion to dismiss, the plaintiff must allege enough factual matter, taken as true, to suggest the required elements of the plaintiff's claims and raise a reasonable expectation that discovery will reveal evidence of these elements. *Id.* In turn, the Court must "draw on its judicial experience and common sense" to find, at minimum, "a reasonable

inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678-79 (2009).

III. DISCUSSION

A. Negligence

Plaintiff argues that Gilead and Asegua negligently designed, manufactured, and failed to warn of the risks of taking Harvoni. (Compl. ¶¶ 13-23.) Under Pennsylvania law, in order for Plaintiff to state a claim for negligence, she must show "that the manufacturer owed a duty to the plaintiff; that the manufacturer breached that duty; and such breach was the proximate cause of plaintiff's injuries," as well as that "the manufacturer was at fault." *Salvio v. Amgen, Inc.*, 810 F. Supp. 2d 745, 752 (W.D. Pa. 2011) (citing *Oddi v. Ford Motor Co.*, 234 F.3d 136, 144 (3d Cir. 2000) and *Parkinson v. Guidant Corp.*, 315 F. Supp. 2d 741, 749 (W.D. Pa. 2004)). The Court addresses each alleged defect in turn.

1. Negligent Failure to Warn

Plaintiff maintains that Gilead and Asegua negligently failed to warn Decedent of the risks of taking Harvoni, including the risk of developing Hepatocellular Carcinoma. But it is well-established in Pennsylvania that prescription drug manufacturers do not owe a duty to warn to the public. *Coyle v. Richardson-Merrell, Inc.*, 584 A.2d 1383, 1385-86 (Pa. 1991). Instead, prescription drug manufacturers owe a duty to warn to the prescribing doctor, who then assesses the medication's risks with the patient. *Id.* at 1386 ("[I]nformation about the risks of medicines is provided to the person who most needs and can be best evaluate it—the physician—to be shared with and explained to the patient in the context of his or her individual medical circumstances."); *Zitney v. Wyeth LLC*, 243 A.3d 241, 246 (Pa. Super. Ct. 2020) ("Under the learned intermediary doctrine, drug manufacturers must direct required drug-safety warning to physicians, and not to

patients."); *Simon v. Wyeth Pharms., Inc*., 989 A.2d 356, 368-69 (Pa. Super. Ct. 2009) (quoting *Taurino v. Ellen*, 579 A.2d 925, 927 (Pa. Super. Ct. 1990)) ("[W]arnings which are required to be given by the manufacturer must be directed to the physician, not the patient-consumer.").

Because Gilead and Asegua had no duty to warn Decedent directly of the risks of Harvoni, and the Complaint does not contain any allegations regarding Decedent's prescribing doctor, let alone any warning (or lack thereof) directed to them, Plaintiff's failure to warn claim fails under Pennsylvania law. Therefore, the Court grants Gilead and Asegua's motion as it relates to their alleged negligence in failing to warn Decedent about the defects or effects of Harvoni.

2. Negligent Design and Manufacturing

Plaintiff also argues that Gilead and Asegua's negligence in designing and manufacturing Harvoni led to Decedent's Hepatocellular Carcinoma. (Compl. ¶ 20). In Pennsylvania, drug manufacturers can be held liable for failing to exercise reasonable care in the manufacture or design processes of a product. *See* Restatement (Second) of Torts §§ 395, 398; *Lance v. Wyeth*, 85 A.3d 434, 445 n.13 (2014) (*Lance II*) (citing *Foley v. Pittsburgh-Des Moines Co.*, 68 A.2d 517, 531 (1949)) ("[T]his Court has rather roundly endorsed the substantive principles reflected in both Sections 395 and 398 of the Restatement Second as having been 'adopted in practically all jurisdictions.'"). Although the Complaint's allegations are not as pointed as one would hope, the Court nevertheless finds that the Complaint contains sufficient facts to plausibly suggest Defendant negligently designed and manufactured Harvoni, and it will not hold against Plaintiff that she is without the tools at this juncture to probe Gilead and Asegua's design and manufacturing processes. *See Wilson v. Synthes U.S.A. Prods., Inc.*, 116 F. Supp. 3d 463, 468 (E.D. Pa. 2015) ("Although these allegations of Plaintiffs' Complaint are not extremely specific, I find that when the complaint is read as a whole, there is sufficient specificity as to the alleged manufacturing

defect to meet the Rule 8 requirement of a 'short and plain statement of the claim.'"). Accordingly, the Court denies Gilead and Asegua's motion as it relates to their alleged negligent design and manufacture of Harvoni. The Court anticipates that Plaintiff will endeavor to begin an exhaustive discovery period regarding her negligent design and manufacturing claims, after which time the Court will entertain any legitimate motions in which Gilead and Asegua may reraise the arguments they made here.

B. Strict Liability

Plaintiff further maintains that Gilead and Asegua are strictly liable for the defective design and manufacture of Harvoni, as well as for failing to warn of the danger of developing liver cancer. (ECF No. 3 at 33-34). But, as Gilead and Asegua correctly argue, such strict liability claims against prescription drug manufacturers are barred under Pennsylvania law.

"Pennsylvania law requires that a plaintiff prove two elements in a strict product liability action: that the product was defective and that the defect was a substantial factor in causing the injury." *Parkinson*, 315 F. Supp. 2d at 746. Pennsylvania follows § 402A of the Restatement (Second) of Torts' strict liability analysis. *Tincher v. Omega Flex, Inc.*, 104 A.3d 328, 359 (Pa. 2014). Comment k to § 402A provides as follows:

> There are some products, which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. . . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. . . . The seller of such products . . . is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.
>
> Restatement (Second) of Torts § 402A cmt. k.

In *Hahn v. Richter*—which involved a failure to warn claim—the Pennsylvania Supreme Court held that Comment k "denies application of strict liability to products such as prescription

drugs, which, although dangerous in that they are not without medical risks, are not deemed defective and unreasonably dangerous when marketed with proper warnings." 673 A.2d 888, 889 (Pa. 1996). Instead, "where the adequacy of warning associated with prescription drugs is at issue," Pennsylvania only recognizes claims for *negligent* failure to warn. *Id.* at 891 (emphasis in original). "Since *Hahn*, Pennsylvania courts have barred strict liability claims based on prescription drug defects." *Terrell v. Davol, Inc.*, Civ. A. No. 13-5074, 2014 WL 3746532, at *4 (E.D. Pa. July 30, 2014). Thus, Gilead and Asegua are immune from Plaintiff's strict liability claims. *See Lance II*, 85 A.3d at 453; *Lance v. Wyeth*, 4 A.3d 160, 453 (Pa. Super. Ct. 2014) (*Lance I*); *Bergstresser v. Bristol-Myers Squibb Co.*, 2013 WL 1760525, at *2 (M.D. Pa. Apr. 24, 2013).

Although Plaintiff suggests that the Pennsylvania Superior Court left open the possibility for strict liability manufacturing defect claims against drug manufacturers in *Lance I*, (ECF No. 7 at 1), she ignores that *Lance I* was reversed in relevant part by *Lance II*, in which the Pennsylvania Supreme Court explicitly foreclosed the availability of those claims. *Lance II*, 85 A.3d at 453 ("For policy reasons this Court has declined to extend strict liability into the prescription drug arena."); *see also Lance I*, 4 A.3d at 165; *Keen v. C.R. Bard, Inc.*, 480 F. Supp. 3d 624, 634 (E.D. Pa. 2020) ("The Pennsylvania Supreme Court has long interpreted comment k to bar strict liability claims in the context of prescription drugs.") (emphasis omitted); *Wilson*, 116 F. Supp. 3d at 466 ("[T]he Pennsylvania Supreme Court had recently resolved this split in *Lance v. Wyeth* . . . where it reiterated the long-standing principle that all strict liability claims are barred in prescription drug cases, and failed to exempt a manufacturing defect claim from this bar."); *Terrell*, 2014 WL 3746532, at *5 ("In accordance with Pennsylvania law, federal district courts have held that in the case of prescription drugs and devices, strict liability claims based on all three defective conditions, including manufacturing defects, are barred in Pennsylvania.").

Therefore, the Court grants Defendants' motion as it pertains to Plaintiff's strict liability claims.

IV. CONCLUSION

For the reasons set forth above, Gilead and Asegua's motion to dismiss is granted in part and denied in part. Gilead and Asegua's motion is granted to the extent it concerns Plaintiff's strict liability claims and her negligent failure to warn claim. Gilead and Asegua's motion is denied to the extent it concerns Plaintiff's negligent design and negligent manufacturing claims. Further, Gilead Science Inc. and Gilead Pharmassett LLC are dismissed as defendants.[2]

An Order consistent with this Memorandum will be docketed separately.

[2] Gilead and Asegua also argue that the Complaint fails because it does not differentiate between the named defendants and thus does not place each defendant on notice of the claims against it pursuant to Fed. R. Civ. P. 8. The Court's dismissal of Gilead Science, Inc. and Gilead Pharmassett LLC, leaving only Gilead Sciences, Inc. and Asegua Therapeutics, Inc. as defendants in this action, should resolve any Rule 8 issues. While the Court appreciates Gilead and Asegua's concern over Plaintiff leaving the Court "to sort out [Plaintiff's] claims conflating various allegations against multiple defendants," the Court further notes that it is an easily searchable matter of public record that Asegua Therapeutics LLC is a subsidiary of Gilead Sciences, Inc., and it is properly named in this action. *See* Gilead Sciences, Inc., Annual Report (Form 10-K) (February 23, 2022) ("[W]e have an authorized generic version of Harvoni distributed by our separate subsidiary, Asegua Therapeutics LLC."); *see also Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993) (citing 5A Charles Allen Wright & Arthur R. Miller, *Federal Practice and Procedure* § 1357 (2d ed. 1990)) (finding that, in a motion to dismiss under Rule 12(b)(6), the court may consider "allegations contained in the complaint, exhibits attached to the complaint and matters of public record").